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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,711

07/28/2006

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

04/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,711	Applicant(s) NISHIMOTO ET AL.	
	Examiner SUSAN HANLEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5,6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5,6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of specie I: directed to a method for transferring a glucosyl group to a polyalcohol with trehalose phosphate in the reply filed on 4/13/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2, 5, 6, 9 and 10 are presented for examination.

Claim Suggestion

It is suggested that the fourth line of claim 2 be changed to read: "reacting trehalose phosphorylase with".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 5, 6, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The are drawn to a method for transferring a glucosyl residue to glucuronic acid and/or a salt thereof by reacting trehalose phosphorylase (TP) with glucose-1-phosphate or trehalose. The method is accomplished with the microorganism *Thermoanaerobium brockii* (ATCC 35047). Applicants disclose that the process is unexpected and surprising.

Since said microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism of the said strain is not so obtainable or available, the requirements of 35 USC 112, first paragraph may be satisfied by a deposit of the microorganisms. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. The specification must contain the date that the microorganism was deposited, the accession number for the microorganism, the name of the microorganism and the address of where the microorganism was deposited.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or hers signature and registration number, **stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent**, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in CFR 1.801-809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or hers signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) a restriction upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

Claims 2, 5, 6, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for transferring a glucosyl residue to glucuronic acid and/or a salt thereof by reacting trehalose phosphorylase (TP) obtained from *Thermoanaerobium brockii* (ATCC 35047) with glucose-1-phosphate or trehalose to obtain the glucosylated glucuronic acid and/or salt thereof that can be purified, does not reasonably provide enablement for said preparation by TP from any possible microorganism including any possible strain of *Thermoanaerobium brockii*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The independent claim is drawn to a method for transferring a glucosyl residue to glucuronic acid and/or a salt thereof by reacting trehalose phosphorylase (TP) from any source with glucose-1-phosphate or trehalose. Claim 5 names properties of the TP and claim 6 recites that the source of the enzyme is from the specie *Thermoanaerobium brockii* or a recombinant enzyme thereof. The specification discloses that the specificity

Art Unit: 1651

of the enzyme is unique in that the ability of the enzyme to react with glucuronic acid is unexpected. The specification shows that microorganisms belonging to the strain *Thermoanaerobium Brockii* (ATCC 35047) are capable of performing the desired glucosyl transfer to glucuronic acid and/or a salt thereof. The limited showing of one TP from one bacterial strain with a particular activity is not sufficient to enable a claim drawn to a TP from any possible microorganism or any strains of said specie because the prior art shows that not all TP enzymes from any possible source can react with glucuronic acid. Kizawa et al. (JP 07284389) teach that TP originated from the genus *Micrococcus* does not accept glucuronic acid as a substrate (see English abstract). Hence, the ability of TP obtained from *Thermoanaerobium Brockii* (ATCC 35047) to accept glucuronic acid as a substrate for glucosylation appears to be a special property that is not common to all TP enzymes.

The specification does not disclose if one skilled in the art can utilize any possible TP obtained from any possible microorganism or strain of *Thermoanaerobium Brockii* to perform the transferase reaction of claim 2 with a reasonable expectation of results. Applicants point out that the ability of TP from *Thermoanaerobium Brockii* (ATCC 35047) to react with glucuronic acid is unexpected. Kizawa et al. confirm that not all TP can be expected to bind and catalyze a reaction with a glucuronic acid substrate. Hence, it appears that the ability of TP to catalyze a reaction with a glucuronic acid substrate is rare and an individual characteristic of said TP from *Thermoanaerobium Brockii* (ATCC 35047). Hence, one skilled in the art would be unable to pick a TP from any microorganism or strain from *Thermoanaerobium Brockii* and expect it to possess

Art Unit: 1651

the same set of properties. If the claimed method is not generally applicable to any TP from any microorganism or strain from *Thermoanaerobium Brockii*, then the desired TP activity from any possible microorganism or strain from said *Thermoanaerobium Brockii* specie would have to be considered individually. This would be considered undue experimentation.

There is no reliable method that predicts which TP from any microorganism or strain from *Thermoanaerobium Brockii* species has the desired glucosyl transferring activity described in the specification. Applicants acknowledge that it was surprising to find that TP from the strain *Thermoanaerobium Brockii* (ATCC 35047) could catalyze a reaction with glucuronic acid or a salt thereof. The prior art confirms that not all TP from any source possess this specificity. The specification does not teach how one of ordinary skill in the art could decide *a priori* which sources will provide TP with the desired characteristics. The limited disclosure cannot be extrapolated by the skilled artisan to predict which microorganism or strains from *Thermoanaerobium Brockii* will produce a TP capable of transferring a glucosyl residue to glucuronic acid. It would require one of skill in the art undue experimentation to determine what sources will provide a TP with the desired activity according to the directions of the instant disclosure. Thus, claims 2, 5, 6, 9 and 10 are not commensurate in scope with the enabling disclosure.

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Susan Hanley/
Examiner, Art Unit 1651